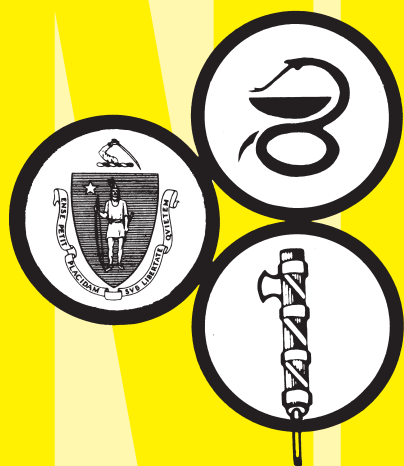


April 2004



# Massachusetts Board of Registration in Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

239 Causeway Street, 5<sup>th</sup> Floor  
Boston, MA 02114

[www.state.ma.us/reg/boards/ph/default.htm](http://www.state.ma.us/reg/boards/ph/default.htm)

## Important Announcements

- 1. Board Elects New President and Secretary:** On December 16, 2003, the Massachusetts Board of Registration in Pharmacy elected James T. DeVita, RPh, president and Karen Ryle, MS, RPh, secretary.
- 2. Donna M. Horn President-Elect of NABP®:** At the National Association of Boards of Pharmacy's (NABP®) 99<sup>th</sup> Annual Meeting in 2003, Donna M. Horn, RPh, past president of the Board of Pharmacy, was elected president-elect of NABP and will go on to serve as its 100<sup>th</sup> president following the 100<sup>th</sup> Annual Meeting in Chicago, IL, April 24-27, 2004.
- 3. Update on Electronic Prescriptions:** As a result of recent passage of a Uniform Electronic Transaction Act (Senate 2076) in Massachusetts, the Board of Registration in Pharmacy (Board) and Department of Public Health (Department) have revised regulations allowing electronic transmission of certain prescriptions for Schedule VI controlled substances. According to the new rules, prescribers will have to abide by new Department regulations at 105 CMR 720.000 et seq. These regulations set the format, security, and confidentiality standards for prescriptions in Massachusetts and can be found on the Department Web site at [www.state.ma.us/dph/dcp/dcp.htm](http://www.state.ma.us/dph/dcp/dcp.htm). Revisions to Board Regulations, effective February 27, 2004 (247 CMR, section 5.02), can be found by visiting the Board's Web site at [www.state.ma.us/reg/boards/ph/cmr/dr/2004\\_prop\\_reg.pdf](http://www.state.ma.us/reg/boards/ph/cmr/dr/2004_prop_reg.pdf).
- 4. Board Develops Ambulatory Root Cause Analysis (RCA) Tool as an Educational and Patient Safety Initiative:** On February 10, 2004, following months of research, the Board reviewed a tool for use by the regulated community that will assist in responding to Quality Related Events (QRE). A QRE is defined as any departure from the appropriate dispensing of a prescribed medication that is not corrected prior to delivery of the medication. This RCA Tool was designed to assist registrants in the process of assessing and preventing QREs. For further information about the complete report and analysis tool, please visit the Board Web site.
- 5. Board Proposes Regulations to Require Quality Assurance Standards in Retail Pharmacies:** As part of its patient safety initiatives, the Board is proposing quality assurance (QA – continuing quality improvement) regulations that will require every Massachusetts-licensed pharmacy to have written policies and procedures in place that must be established “for the purpose of detecting, documenting, assessing and preventing Quality-Related Events. . . .” The regulations will also require annual professional education in the area of QA for pharmacists, registered technicians, and registered interns.
- 6. USP Announces New Standard:** Pharmacists should be reminded that Board regulations [247 CMR, 9.01 (3)] state: “a pharmacist shall observe the standards of the current United States Pharmacopoeia [USP].” Pharmacists are likely aware that USP has issued new standards: “Standard 797 Pharmaceutical Compounding – Sterile Preparations,” which became effective January 1, 2004. Pharmacists in all regulated practice settings are expected to follow this standard when compounding sterile preparations. For instructions on obtaining a copy of the standard, visit USP's Web site at [www.usp.org](http://www.usp.org).
- 7. NABP and FDA Form Alliance in Attacking the Problem of Counterfeit Drugs:** On February 18, 2004, United States Department of Health and Human Services Secretary (HHS) Tommy Thompson, Food and Drug Administration (FDA) Commissioner Mark McClellan, and NABP Executive Director/Secretary Carmen A. Catizone, MS, RPh, DPh, held a joint press conference to announce FDA's Task Force Report on counterfeit drugs, “Combating Counterfeit Drugs” ([www.fda.gov/oc/initiatives/counterfeit/report02\\_04.html](http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html)) NABP and FDA have joined forces in dealing with this emerging threat and NABP has developed new model regulations for the licensing of drug wholesalers that NABP and FDA are asking member boards of pharmacy to adopt. These model regulations will require appropriate background checks of key employees, and electronic tracking requirements by 2007, called “pedigrees,” which trace the movement of prescription drugs from manufacture to dispensing. NABP will also develop a clearinghouse of information on these wholesalers and has provided a list of drugs most suspected of being copied by clandestine operations. For further information, visit NABP's Web site at [www.nabp.net](http://www.nabp.net).
- 8. From the President – James T. DeVita, RPh:** It is our Mission at the Board of Pharmacy to promote, preserve, and protect the health, safety, and welfare of the citizens of the Commonwealth by fostering the delivery of quality pharmaceutical care. To accomplish this Mission, the Board must assume a leadership role in regulating the practice of pharmacy and act in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and open communication. In 2004, the Board of Pharmacy will focus its resources on goals that will advance patient safety, reduce pharmacist workload, and improve communication with its registrants. Initiatives such as electronic prescribing, collaborative practice, pharmacist immunization, compounding guidelines, and continuous quality improvement regulations are well underway. The purpose of this quarterly *Newsletter* is to offer information regarding the latest developments within the Board

*Continued on page 4*

Continued from page 1

and provide direction to additional informational resources. Future *Newsletters* will highlight specific areas of interest and offer guidance for new initiatives.

As the profession continues to evolve, timely communication will be a vital component to the success of the practice of pharmacy. I encourage registrants to read the *Newsletters*, visit our Web site, and attend our public Board meetings.

**9. Quality Assurance – Recent Cases Reviewed by the Board:**

Look-alike/Sound-alike Drugs: **Be Aware**

Keppra®/Kaletra®

Metaproterenol/Metoprolol

Clonidine/Colchicine

Mysoline®/Minocin®

Seroquel®/Serzone®

Zantac®/Zyrtec®

Zestril®/Zerit®

Clomiphene/Clomipramine

**10. Best Practice Recommendation of the Month:** As you are likely aware, the Board developed a set of 21 Best Practice Recommendations in 2003 that the Board believes may assist in reducing medication errors, improving the quality of drug delivery, and optimizing patient outcomes. These recommendations may be found on the Board's Web site at [www.state.ma.us/reg/boards/ph/misc/bprac.htm](http://www.state.ma.us/reg/boards/ph/misc/bprac.htm). The Board finds pediatric medication errors of particular concern and this month's *Newsletter* will feature Best Practice Recommendation No. 8, which recommends: **"Utilize available age-adjusted dosing guidelines when appropriate."**

Recommended Actions

- ◆ Verify pediatric dosing to ensure proper dose.
- ◆ Develop pediatric- and geriatric-specific guidelines for age-adjusted dosing.
- ◆ Consider acquiring or utilizing reference materials, textbooks, and/or computer software that directly address pediatric and geriatric dosing.
- ◆ When appropriate and necessary, verify that doses are appropriate for the patient.

In addition, the Board strongly recommends (as set forth in Best Practice Recommendation No. 6) that the pharmacist make an attempt to counsel on each pediatric new and refill prescription.

**11. HHS Announces New Requirements for Bar Codes on Drugs and Blood to Reduce Risk of Medication Errors:**

On February 25, 2004, HHS Secretary Tommy Thompson announced that FDA issued a final rule requiring bar codes on the labels of thousands of human drugs and biological products. This final rule will require linear bar codes on most prescription drugs and on over-the-counter drugs **commonly**

**used in hospitals** and dispensed pursuant to an order. For blood and blood components intended for transfusion, the final rule requires the use of machine-readable information in a format approved for use by FDA. For a complete copy of the report and press release, visit the following link:

[www.fda.gov/oc/initiatives/barcode-sadr/](http://www.fda.gov/oc/initiatives/barcode-sadr/).

**Recent Board Policies**

For a complete list of all Board policies visit our Web site at:

◆ [www.state.ma.us/reg/boards/ph/default.htm](http://www.state.ma.us/reg/boards/ph/default.htm)

◆ [www.state.ma.us/reg/boards/ph/pol000000.htm](http://www.state.ma.us/reg/boards/ph/pol000000.htm)

Please consider providing feedback to the Board about your comments/suggestions about this and future *Newsletters*. Remember, this *Newsletter* is for you, so feel free to send recommendations for future *Newsletters* by e-mail to [charles.r.young@state.ma.us](mailto:charles.r.young@state.ma.us) or [james.d.coffey@state.ma.us](mailto:james.d.coffey@state.ma.us).

Thank you.

**Board Member List**

James T. DeVita, RPh..... President

Karen Ryle, RPh, MS..... Secretary

Donna M. Horn, RPh..... Member

Dan Sullivan, RPh..... Member

Harold Sparr, RPh, MS..... Member

Marilyn Barron, MSW..... Public Member

**Staff**

Chuck Young, RPh, CFE..... Executive Director

J. D. Coffey, RPh..... Associate Director

Susan Manning, Esq..... Administrative Counsel

Arthur J. Chaput, PharmD, RPh..... CQI Surveyor

Lau Kwan..... Administrative Assistant

Carolyn Reid..... Administrative Assistant

**Enforcement Agents (Office of Public Protection)**

Leslie Doyle, RPh, Supervisor.....617/727-5970

James Emory, CPhT.....617/727-1803

---

Page 4 – April 2004

The *Massachusetts Board of Registration in Pharmacy News* is published by the Massachusetts Board of Registration in Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Charles R. Young, RPh, CFE - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Reneeta C. "Rene" Renganathan - Editorial Manager

---

Presorted Standard  
U.S. Postage  
PAID  
Chicago, Illinois  
Permit No. 5744

National Association of Boards of Pharmacy Foundation, Inc.  
700 Busse Highway  
Park Ridge, Illinois 60068  
MASSACHUSETTS STATE BOARD OF PHARMACY